Texas Department of State Health Services
Radiation Safety Licensing Branch

Regulatory Guide 2.2

GUIDE FOR APPLICATIONS FOR EVALUATION OF SEALED SOURCES OF RADIOACTIVE MATERIAL

I. Introduction.

This guide has been prepared to assist manufacturers/distributors in the preparation of applications for evaluation of radiation safety information on the design for sealed sources containing radioactive material.

II. Evaluation fees.

A. A fee is required for evaluations of sealed sources and must be submitted with any request for evaluation. The applicant should refer to 25 Texas Administrative Code (TAC) '289.204 (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services) to determine the fee that should accompany the request. The evaluation will not begin until the proper fee is received by the agency. The check or money order should be made payable to the Texas Department of State Health Services (DSHS or agency).

B. Questions on fees may be directed to the accounting staff at 512-834-6688.

III. Specifications and style.

Review, handling and filing of applications can be facilitated by observing the following guidelines on specifications and style.

Regulatory Guides are issued to assist applicants and licensees/registrants in developing operational procedures acceptable to the Department of State Health Services, Radiation Safety Licensing Branch (agency), that are compliant with specific sections of Title 25 Texas Administrative Code Chapter 289. Regulatory Guides are NOT substitutes for regulations and compliance with them is not required. Methods for compliance with regulations different from those set out in guides will be acceptable if they are considered by agency staff to provide for public health and safety and demonstrate compliance with

Comments and suggestions for improvements in Regulatory Guides are encouraged. Letters containing comments and suggestions should be sent to the Department of State Health Services, Attn: Manager, Radioactive Material Licensing – MC 2835 P.O. Box 149347 Austin, Texas 78714-9347. Regulatory guides may be reproduced or may be obtained by contacting the agency at (512) 834-6688 or accessing the agency web page at www. dshs.state.tx.us/radiation

(October 2008)

A. Physical specifications.

All pages in an application should be numbered consecutively. Text pages should be printed on two sides with the image printed head to head.

1. If revisions are necessary after submission of an application, revised pages should be submitted. Each revised page should be numbered and show the date of revision. The revised portion of the page should be marked by a bold vertical line in the margin opposite the binding margin. If supplemental pages are submitted as part of the revision, they may be indicated alphanumerically (for example, 13a, 13b, etc).

2. The preferred paper size is 8 2 x 11 inches. If a larger size is used, the page, after reduction, should not exceed 11 x 17 inches, including a 1-inch margin at the left for binding. The finished copy should not exceed 8 2 x 11 inches when folded.

3. A margin of no less than one inch should be maintained on the top, bottom, and binding side of each page.

4. All drawings should have a drawing number, revision number, company name, title, date, and page number.

5. Type of paper, color of paper and ink, type font and style, and printing or reproduction method should be suitable for microfilming.

B. Style and composition.

The applicant should present the information provided in the application in a clear, concise manner, omitting ambiguous statements and wordy descriptions that do not contribute to expeditious technical review. Claims of adequacy of designs or design methods should be supported by technical data i.e., by an appropriate engineering evaluation or description of actual tests. Terms as defined in 25 TAC '289 and American National Standards Institute (ANSI) should be used.

Appendices may be used to include detailed information omitted from the main text. All physical tests should be supported by photographs in the appendices.

Where numerical values are stated, the number of significant figures given should reflect the accuracy and/or precision to which the number is known. Where possible, estimated limits of error or uncertainty should be given.

Abbreviations not in general use should be defined.

IV. Summary data.

This section should be presented on one page [Appendix A, Sample Summary Data Sheet].

A. Date - Date of submission.

B. Sealed source - Insert the short name commonly used by the manufacturer/distributor to identify or describe the source and the type of radiation emitted.

C. Model - Model number(s) or series number(s) used by the manufacturer/distributor to identify the sealed source.

D. Applicant - Name and complete mailing address of the organization submitting the application. Indicate whether it is the manufacturer or distributor or both, and include the name, title, and telephone number of the person to be contacted for further information.

E. Other companies involved - Name and address of any other companies directly involved in the manufacture or distribution of this sealed source. For example, if the applicant distributes a sealed source manufactured by the XYZ Company, list: XYZ Company, Manufacturer, and give the mailing address.

F. Isotope and maximum activity - List the radionuclide(s) proposed for use in the sealed source and the maximum acceptable activity level in curies or millicuries for each isotope. Indicate the SI units in parenthesis [e.g. 1 Ci (37 GBq)].

G. Leak test frequency - State the proposed frequency for testing the sealed source for possible leakage of radioactive material [Section VI.B.3., "Leak testing during use"].

H. Principal use - Select the term that most accurately describes the principal or predominant use intended for the sealed source [Appendix B, "Standard List and Definitions, Principle Uses of Sealed Sources and Devices"].

I. Custom source - Indicate whether or not the sealed source is a custom source. Present the basis for this determination. Sealed sources specifically designed and constructed according to the personal order of a single specific license applicant may be considered "CUSTOM" sealed sources for the purpose of a review tailored to the single applicant. Sealed sources designed and constructed as off-the-shelf items or for use by more than a single license applicant will not be deemed applicable to custom reviews and will not be considered for a custom review and registration. NOTE: A sealed source used by a single company having multiple licenses in multiple regulatory jurisdictions will not be classed as

a "CUSTOM" source.

J. Custom user - If a custom source, give the name and address of the custom user.

V. Descriptive data.

This section should include a detailed description of the sealed source. A checklist has been included to assist you in providing the information required in Section V. A. - C. [Appendix C, "Checklist for Radiation Safety Evaluation"].

A. Description.

Provide an accurate, yet concise, description of the sealed source, including information on the chemical and physical form of each nuclide, the materials used in the capsule construction, capsule dimensions and the methods for fabrication and sealing of the capsules. State the ANSI classification designation of the source, obtained from ANSI/HPS Standard N43.6-1997. Some of this information may be found in sales brochures and pamphlets. Note: Only sources containing americium-241, plutonium and radium-226 may be distributed as generally licensed sources for the purposes of calibration, stabilization, or reference. Do not include information that has been determined to be proprietary data in this item [Section V.F., "Supporting detail" and Appendix D, "Exceptions to Public Access"].

B. Labeling.

Describe the information to be engraved, etched, or imprinted on a sealed source and the type and location of warning labels. The label for a sealed source should include the words: "DANGER - RADIOACTIVE MATERIAL" or "CAUTION - RADIOACTIVE MATERIAL," the manufacturer's name or trademark, model number, serial number, radionuclide, activity, assay date, and the radiation symbol. Where labeling the source is impracticable, a tag containing the above information should be attached to the source, unless the attachment of such a tag is also impracticable. The serial number of the source should always be on each sealed source to aid in identification. When a sealed source is permanently mounted in a device, source labeling is not required, provided the device is labeled as specified above. For the generally licensed sources referenced on the previous page, a specific label is required. That label must contain the following information:

The receipt, possession, use, or transfer of this source, Model _____, Serial No._____, are subject to a general license and the regulations of the Nuclear Regulatory Commission (NRC) or an agreement state. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM-238) (PLUTONIUM-239) (Show only the name of the appropriate material.). DO NOT TOUCH THE RADIOACTIVE PORTION OF THIS SOURCE.@ _____

Name of manufacturer or importer

The receipt, possession, use, or transfer of this source, model_____, serial no._____, are subject to a general license and the regulations of any licensing state. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH THE RADIOACTIVE PORTION OF THIS SOURCE. @

_____

Name of Manufacturer or Importer

C. Drawing.

Provide a drawing of the sealed source showing the construction materials, dimensions, method of sealing, and relationships of major components. Do not include information that has been determined to be proprietary data in this item. Additional drawings depicting the labeling and use may also be submitted. These drawings may be submitted on a computer diskette in one of the graphic formats in Appendix E, "Acceptable Graphics Formats"].

D. Conditions of normal use.

Describe the planned use of the sealed source and identify the environment and operating conditions expected during normal use (maximum allowable temperature, vibration, shock, corrosion, etc.). Include descriptions of the types of uses, locations of use, possibilities of use as a component in other products, and circumstances of normal use. Indicate the expected useful life of the source.

E. Limitations of use.

Describe the probable effects of severe conditions, including accidents and fires. Include the maximum temperature, vibration, shock, corrosion, etc. that can occur before failure of the sealed source.

F. Supporting detail.

Provide a design package containing drawings of the sealed source, identifying all methods of construction, dimensions, methods of fabrication, and method of sealing the source capsule(s) in detail sufficient to allow a comprehensive safety evaluation.

If the information presented in the supporting data contains information that the applicant considers to be proprietary data, such data should be clearly marked so that it can be handled appropriately. In addition, the letter transmitting the application should call attention to the inclusion of proprietary data [Appendix D, Exceptions to Public Access].

Provide references to other pertinent documents, including previous applications and registration sheets for similar sealed sources.

VI. Health and safety data.

This section should include information on the requirements for the safe handling and use of the sealed source.

A. Safety analysis summary.

Provide a paragraph that summarizes the information contained in Section VI.B., "Manufacturer's safety analysis of sealed source review," the important facts pertaining to safety, and the results of the safety analysis performed by the manufacturer/distributor. Include references to the appropriate ANSI, National Bureau of Standards (NBS), NRC, or agency standards used in the safety analysis.

B. Manufacturer's safety analysis of sealed source review.

Each application for a sealed source review should include a section that contains the manufacturer's Safety Analysis Report. The Safety Analysis Report determines the ability of the final design to withstand the normal conditions of handling, use, and storage, including such factors as abrasion, corrosion, vibration, impact, puncture, and the probable effects on containment of abnormal conditions such as fire or explosion. It should contain the following information and any additional information that will clarify the safety of the sealed source.

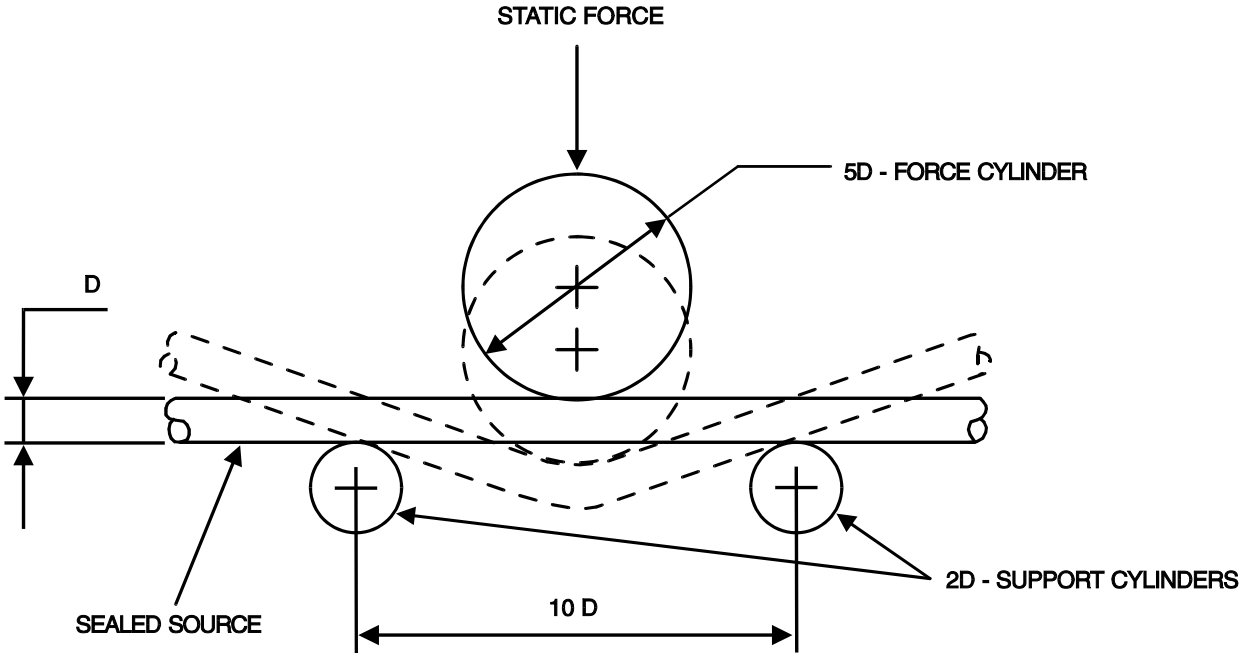
1. Prototype testing and evaluation.

Describe the tests performed on each prototype sealed source and submit the test results that establish the integrity of the radiation safety features of the sealed source under the conditions of use to which the source is likely to be subjected.

Include the results of tests performed on prototype sources that establish the integrity of the source construction and seal under the most likely adverse conditions of use. These prototype tests should, insofar as possible, reflect the actual conditions of use and should meet the designated usage

classification according to the current ANSI/HPS 43.6-1997 entitled "Sealed Radioactive Sources Classification," provided the means for assigning such a classification is described.

For sealed sources with an active length (L) to minimum outer capsule diameter [or smallest cross-sectional dimension of non-circular sources] (D)



ratio of 15 or greater, a bend test is required. Bend test classifications are based on applied static force using the following test parameters. All three cylinders shall not rotate and shall have longitudinal axes that are parallel to each other. The cylinders shall have smooth surfaces and shall be of sufficient length to accommodate the full contact surface of the capsule during the test procedure. All cylinders are to be of a solid nature. Cylinder hardness should be of a hardness rating of Rockwell >C= 50 - 55. In applying the static force, care should be taken not to apply this force suddenly as this will increase the effective force.

BEND TEST	CLASS						
	1	2	3	4	5	6	X
STATIC FORCE	NO TEST	100 N (10.2 kg)	500 N (51 kg)	1,000 N (102 kg)	2,000 N (204 kg)	4,000 N (408 kg)	SPECIAL TEST

The applicable static force shall be applied at the most vulnerable part of the sealed source. (Note that at the printing of this guide, this test was not required in ANSI/HPS N43.6-1997. It will probably be included in the next revision of that standard.) For many sealed sources, guidance on design considerations, tests of prototypes and quality control program are provided in industry or consensus standards. Applicants for safety evaluations are

encouraged to consider such guidance. The following standards are particularly useful:

- Sealed radioactive source classification - ANSI/HPS N43.6-1997, "Sealed Radioactive Source - Classification," and ISO.2919-1980, "Sealed Radioactive Sources - Classification@

- Brachytherapy - ANSI N44.1-1973, "Integrity and Test Specifications for Selected Brachytherapy Sources@

- Radiography - ANSI N432, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography"

- Gauges - ANSI N538, "Classification of Industrial Ionizing Radiation Gauging Devices"

- Irradiators - ANSI N433.1, "Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators (Category I)," and N43.10, "Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV)"

- Self-luminous light sources - ANSI N540, "Classification of Radioactive Self-Luminous Light Sources"

- Teletherapy - National Council on Radiation Protection (NCRP) Report No. 33, "Medical X-Ray and Gamma-Ray Protection for Energies up to 10 MeV"

- Smoke detectors - Nuclear Energy Agency, (NEA) "Recommendations for Ionization Chamber Smoke Detectors in Implementation of Radiation Protection Standards" 1977

If there is no specific industry or consensus standard for your sealed source, obtain useful general guidance from a standard for a comparable source. ANSI N538 may be particularly useful for general guidance on quality control. The standards listed in this paragraph are available from the following sources.

- ANSI and International Standards Organization (ISO)
  American National Standards Institute
  1430 Broadway
  New York, NY 10018

$ NCRP reports

The National Council on Radiation Protection and Measurements
7910 Woodmont Avenue
Washington, DC 20014

$ NEA reports

Organization for Economic Cooperation and Development
Publications and Information Center
1750 Pennsylvania Avenue NW
Washington, DC 20006

In some instances, engineering analyses may be an acceptable alternative to testing of prototypes. For example, engineering analyses may be appropriate for custom sealed sources, sources expected to have limited distribution or low potential hazard, or sources that are quite similar to previously tested prototypes. Even in these instances, the applicant should submit historical use data or data from tests on prototypes of similar sources to reinforce findings from engineering analyses.

Source manufacturers frequently evaluate their products to determine the effects of the tests for special form radioactive material [Title 10, Code of Federal Regulations (CFR), '71.77, "Packaging and Transportation of Radioactive Material"]. If these tests are performed, the results of the tests should be submitted. If a national entity that has the authority to issue special form requirements for transportation has issued a certificate stating that the sealed source satisfies the special form requirements for transportation purposes, a copy of that certificate should be included in the application for safety evaluation and registration of the sealed source.

2. Radiation levels.

Submit radiation profiles or other statements of radiation levels associated with the sealed source. Radiation levels should be determined using the maximum activity of each radionuclide expected to be used in the source. In general, the distances for determining the radiation levels are 5 centimeters (cm), 30 cm, and 100 cm from the source to the effective center of the radiation measuring chamber. A description of the method and instrumentation used to measure the radiation levels or the bases for calculations used to determine the levels should be included.

For sealed sources that emit more than one type of radiation, the contribution of each type should be provided as well as the total radiation level. For example, for an Am-241/Be neutron source used in well logging, both the

gamma contribution and the neutron contribution should be provided. This information is important in determining radiation levels external to well logging tools and storage containers.

Occasionally a source may contain a radioactive contaminant, or the principal radionuclide may not be in equilibrium with its daughter products at the time of initial determination of radiation levels.

Accordingly, subsequent determinations may show radiation levels that are significantly different from levels calculated by adjusting the initial determination for decay of the principal radionuclide. If this condition applies to your sealed source, you should describe the expected changes in the energy spectrum and radiation levels during the probable useful life of the source.

3. Leak testing during use.

   '289.201(g) requires, with certain exceptions, that sealed sources be tested periodically for possible leakage of radioactive material at intervals not to exceed six months. However, an applicant may request a longer interval. A leak test interval longer than six months should address the subjects listed in '289.252(l) or (o), as applicable, and the quality control measures that ensure an absence of leakage and contamination.

   There is an exemption from the periodic leak testing of a sealed source in accordance with '289.201(g) if the sealed source contains only hydrogen-3, radioactive material with a half-life less than 30 days, radioactive material in the form of gas, less than 100 microcuries (ΦCi) of beta- or gamma-emitting material, or less than 10 ΦCi of alpha-emitting material. However, distributors of these sealed sources must ensure that they are free of leakage and contamination when transferred.

4. Documentation accompanying the sealed source.

   Submit a sample of or describe radiation-safety-related documentation to be supplied with the sealed source. Examples of documentation include:

   - $ certificate providing the date and results of the most recent leak test and contamination check
   - $ statement identifying the primary radionuclide and its quantity and the identity and quantity of other radionuclides in the sealed source
   - $ copy of a "special form" certificate issued by a national entity that has the authority to issue special form requirements for transportation as defined in Title 10, CFR, '71.4
   - $ statement of the ANSI or ISO source classification
   - $ statement of the radiation output of the source
   - $ any safety recommendations or warnings with respect to unpacking, handling, storing, etc., to be used to minimize exposure to user personnel

C. Manufacturing and distribution controls.

   Describe the quality control program and the procedures to be followed to ensure that each finished sealed source meets specifications furnished to the agency.

Even for a custom sealed source, provide a copy of the procedures to be followed or tests to be performed to ensure that the finished custom sealed source meets your design specifications [Appendix F, "Development of a Quality Assurance/Quality Control Program"].

A particularly important portion of the quality control program is ensuring that the sealed source is not leaking and is free of contamination at the time of transfer to the user. Generally, this means the absence of 0.005 ΦCi or more of removable radioactive material.

Describe the quality control procedures to be followed in the selection of raw materials, in the fabrication of production lots of the sources, as applicable, and the quality control standards for maintaining source design specifications [Appendix F, "Development of a Quality Assurance/Quality Control Program"].

Describe the assay method used to determine the radioactive content of the sealed source. This method should be traceable to a national standard.

Describe the manufacturer's recommendation for leak testing, unpacking, handling, and disposal of the sealed source and specify availability of these services.

Each manufacturer, assembler, or distributor must perform a leak test on each source by applying procedure(s) in the current ANSI/HPS N43.6-1997, "Sealed Radioactive Sources - Classification." Acceptability of source leakage must be indicated by removal of less than 0.005 ΦCi of radioactive material [' 289.201(g)].

VII. Amendments to registration certificates for sealed sources.

It is the licensee=s obligation to keep the registration certificate for the sealed source current. If the information provided in the application or in the certificate is modified or changed, submit an application to amend the certificate. Until an amendment is granted, continued compliance with the information in the current certificate is required.

An application to amend a certificate should be prepared in duplicate. Submit the original and retain one copy for your records. The application should identify the registration certificate by number and should clearly describe the changes and the effects of the changes on the safety properties of the sealed source. For example, to change the radionuclide or increase the radioactivity limit and source dimensions, the application for an amendment should identify the new radionuclide or quantity limit, the new radiation levels, and the effects on the ANSI classification for the source. References to previously submitted information should be clear and specific and should identify that information by

date, document title, and page number.

VIII. Medical sources.

If a source is to be used for medical purposes and is subject to regulation by the United States Food and Drug Administration (FDA), a registration certificate will not be issued unless the applicant has submitted an FDA 510k Certificate or similar indication of marketing approval by FDA to the NRC. Information on FDA requirements may be obtained by contacting:

United States Food and Drug Administration
Center for Devices and Radiological Health
HFZ-4O1
8757 Georgia Avenue
Silver Spring, MD 20910

IX. Registration of a foreign-manufactured source.

A sealed source manufactured outside the United States may be registered by the agency if the appropriate information is supplied and if the agency's administrative requirements are satisfied. The registrant must establish a licensed facility in Texas where papers may be served, records required by 25 TAC ‘289 will be maintained, and the agency can inspect the registrant's activities as necessary to fulfill the requirements of 25 TAC ‘289.

A licensee in Texas may elect to import a source that will be manufactured in a foreign country in accordance with specifications determined by that licensee. Under these conditions, the licensee should register the appropriate radiation safety information with the agency.

Appendix A
Sample Summary Data Sheet

An Application for Safety Review

Date: February 29, 1999

Sealed Source Type: Gamma Backscatter Source

Model: AB-200

Applicant: XYZ Company
123 Main Street
Anytown, Texas 99999
Tel. (999) 123-4567
Contact: John Q. Public, Chief Engineer

Other Companies Involved: ABC, Inc. (manufacturer of secondary containment capsule)
124 Main Street
Anytown, Texas 99999
Tel. (999) 123-4568
Contact: Abel B. Public

Isotope and Maximum Activity: Cs-137 - 100 millicuries (mCi) (3.7 GBq)

Leak Test Frequency: 6 Months

Principal Use: D (Gamma Gauges)

Custom Source: No

Custom User: N/A

Appendix B

STANDARD LIST AND DEFINITIONS
PRINCIPAL USES OF SEALED SOURCES AND DEVICES

CODE

A Industrial Radiography - The examination of the structure of materials by nondestructive methods, utilizing sealed sources of radioactive material.

B Medical Radiography - The process of producing x-ray or gamma-ray images to assist in the determination of medical diagnoses.

C Medical Teletherapy - The treatment of disease with gamma radiation from a controlled source of radiation located at a distance from the patient.

D Gamma Gauges - The use of gamma radiation to measure or control thickness, density levels, interface location, radiation leakage, or chemical composition.

E Beta Gauges - The use of beta radiation to measure or control thickness, density levels, interface location, radiation leakage, or chemical composition.

F Oil Well Logging - The lowering and raising of measuring devices or tools that may contain radioactive sources into well bases or cavities for the purpose of obtaining information about the well and/or adjacent formations.

G Portable Moisture Density Gauges - Portable gauges that use a radioactive sealed source to determine or measure moisture content or density of material. This includes hand-held or dolly-transported devices or sources.

H General Neutron Source Applications - All applications, excluding reactor start-up, that use a neutron source.

I Calibration Sources (Activity greater than 30 mCi) - Sources of a known purity and activity that are used to determine the variation in accuracy of a measuring instrument and to ascertain necessary correction factors.

J Gamma Irradiator, Category I - An irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid

materials, is shielded at all times, and human access to the sealed source(s) and the volume(s) undergoing irradiation is not physically possible in its design configuration.

Appendix B (Continued)

STANDARD LIST AND DEFINITIONS
PRINCIPAL USES OF SEALED SOURCES AND DEVICES

CODE

K Gamma Irradiator, Category II - All applications that are panoramic and use dry source storage for irradiation of biologic or other materials.

L Gamma Irradiator, Category III - Applications that are self contained and use a wet source storage for irradiation of biologic and other materials.

M Gamma Irradiator, Category IV - Applications that are panoramic and use a wet source storage for irradiation of biological and other materials.

N Ion Generators, Chromatography - Process of using an ion generating source to determine the chemical composition of material.

O Ion Generators, Static Eliminators - Process of using an ion generating source to eliminate static electricity on a surface or a surrounding area.

P Ion Generators, Smoke Detectors - Process of using ion generating sources to detect gases and particles created by combustion.

Q Thermal Generator - Process of using radioisotope heat to produce energy.

R Gas Sources - Sealed sources containing radioactive gas such as ^{85}K or 3H.

S Foil Sources - Sources that are constructed using thin metal foil. The radioactive material may be secured to the foil in a number of ways, for example: plating, laminating, or cold welding.

T Other - All other uses or applications not covered in other categories.

U X-Ray Fluorescence - Sources and/or devices utilizing radioactive material that excites the atoms of samples which, in turn, emit characteristic x-rays, and thereby, provide a means for sample analysis.

V General Medical Use - This category includes diagnostic sources and devices (bone mineral analyzers) and therapeutic sources and devices

(interstitial needles, therapeutic seeds, and ophthalmic applicators).

W Medical Reference Sources - Including flood sources, instrument check sources, spot markers, etc.

APPENDIX C
CHECKLIST FOR SEALED SOURCE RADIATION SAFETY EVALUATION

This checklist may be helpful to an applicant when compiling an application for a sealed source safety evaluation. This checklist does not need to be submitted with the application. Certain items in this list are not appropriate for all sealed sources, e.g., neither a 0.1 ΦCi Am-241 source used in a smoke detector nor a 2 mCi gaseous tritium self-luminous light source is required to be leak tested by the user. Accordingly, when using the checklist for these sources, entries of "Not Applicable" would be made as appropriate under "Leak test frequency."

_____ Registrant's name and address

_____ Manufacturer's name and address (may be same as registrant)

_____ Sealed source type

_____ Sealed source model

_____ Radionuclide(s) and maximum activity of each

_____ Leak test frequency

_____ Description

- _____ Written description
- _____ Small drawing
- _____ ANSI/HPS N43.6-1997 classification

_____ Conditions of use

_____ Details of construction

- _____ Radioactive material (Chemical and physical form: possible radioactive contaminants)
- _____ Materials of construction
- _____ Dimensions
- _____ Fabrication and sealing methods

_____ Labeling

_____ Radiation levels and methods of determination

_____ Quality control (Including leak/contamination test limits)

_____ Documentation accompanying source

Appendix D

EXCEPTIONS TO PUBLIC ACCESS

A. Statutory exceptions

Rules pertaining to open records are found in 25 TAC '289.201, "General Provisions for Radioactive Material." The Texas Public Information Act, Government Code, Chapter 552, requires that all information filed with a state agency be accessible upon request unless it falls within exceptions listed in the statute. The exceptions most likely to apply to a licensee are the following:

'552.101 A...information considered to be confidential by law, either constitutional, statutory, or by judicial decision;@

'552.104 A...information that, if released, would give advantage to a competitor or bidder;@

'552.110(a) A...trade secret obtained from a person and privileged or confidential by statute or judicial decision;" or

'552.110(b)A...commercial or financial information for which it is demonstrated based on specific factual evidence that disclosure would cause substantial competitive harm to the person from whom the information was obtained...@

B. Marking of documents

1. Documents containing information that falls within an exception to the Texas Public Information Act shall be marked to indicate that fact. Markings shall be placed on the document on origination or submission.

2. The words ANOT AN OPEN RECORD@ shall be placed conspicuously at the top and bottom of each page containing information claimed to fall within one of the exceptions.

The following wording shall be placed at the bottom of the front cover and title page, or first page of text if there is no front cover or title page:

"INFORMATION FALLING WITHIN EXCEPTION OF THE TEXAS PUBLIC INFORMATION ACT, GOVERNMENT CODE, CHAPTER 552---CONFIDENTIAL"

Appendix D (Continued)

EXCEPTIONS TO PUBLIC ACCESS

This document contains information submitted to the Texas Department of Health, Bureau of Radiation Control by

_____
(Name of Company) (Name of Submitter)

which is claimed to fall within the following exception to the Texas Public Information Act, Government Code, Chapter 552, Subchapter C _____.

(Appropriate subsection)

WITHHOLD FROM PUBLIC DISCLOSURE

_____
(Signature and Title) (Office) (Date)

Include a legal brief justifying the exception of the attached or marked material, including statutes and cases, where applicable.

3. The agency requests, whenever possible, that all information submitted under the claim of an exception to the Texas Public Information Act be extracted from the main body of the application and submitted as a separate annex or appendix to the application. This procedure will facilitate the processing of the application.

4. Failure to comply with any of the above procedures may result in all information in the agency file being disclosed upon an open records request.

D. Determination of exception under the Texas Public Information Act

The agency will determine whether information falls within one of the exceptions to the Texas Public Information Act. The Office of General Counsel will be queried as to whether or not there has been a previous determination that the information falls within one of the exceptions to the Texas Public Information Act. If there has been no previous determination and the agency believes that the information falls within one of the exceptions, an opinion of the Attorney General will be requested. If the agency agrees in writing to the request, the information shall not be open for public inspection unless the Attorney General's office subsequently determines that it does not fall within an exception.

Appendix E - Acceptable Graphics Formats

RASTER		VECTOR		METAFILE	
ATT	ATT&T Group 4	CGM	CGM Metafile	AI	Encapsulated PS
BMP	Windows OS/2 Bitmap	DXF	AutoCAD	CDR	CorelDRAW
CAL	CALS Raster	EPS	Encapsulated PostScript	CLP	Windows Clipboard (source only)
CLP	Windows Clipboard (source only)	GCA	IBM GOCA	DRW	Micrografx Draw
CPR	Knowledge Access (source only)	GEM	GEM Metafile	PCT	Macintosh PICT 2
CUT	Dr. Halo	IGF	Inset Systems IGF	WMF	Windows Metafile
DBX	DataBeam	MCS	MathCAD (destination only)	WPG	Wordperfect Graphic
DIB	Windows OS/2 Bitmap	MET	PM Metafile (destination only)		
ED5	EDMICS (source only)	P10	Tektronix Plot P10 (source only)		
ED6	EDMICS (source only)	PDW	HiJaak Draw		
EPS	Encapsulated PostScript	PGL	HP 7475A Plotter		
FAX	Fax Type	PIC	Lotus PIC		
GED	Wicat	PIX	Inset Systems PIX		
GIF	CompuServe	TXT	ASCII Text		
ICA	IBM IOCA				
ICO	Windows Icon				
IFF	Amiga ILBM				
IGF	Inset Systems IGF				
IMG	GEM Paint				
JPG	JPEG				
KFX	Kofax Group 4				
MAC	MacPaint				
MSP	Microsoft Paint				
NIF	Navy Image File Format				
PCD	Photo CD (source only)				
PCL	HP LaserJet II				
PCX	PC Paintbrush				
PIX	Inset Systems PIX				
RAS	Sun Raster				
RLC	Image Systems				
RLE	Windows OS/2 Bitmap				
SBP	IBM Storyboard PIC (source only)				

TGA	Truevision
IF	Tagged Image File Format

Appendix F

DEVELOPMENT OF A QUALITY ASSURANCE/QUALITY CONTROL (QA/QC) PROGRAM

I. Definitions

The following definitions apply for the purposes of this appendix.

Nonconforming materials - Materials (parts, subassemblies, assemblies, or devices) that do not meet the standards or specifications of design.

Sample - One or more units of product drawn from a lot or batch, the units of the sample being drawn without regard to their quality.

Sample size - The number of units of product in the sample selected for inspection.

Subcontractor - Any person, persons, or company that supplies material, equipment, or services to a vendor.

Vendor - Any person, persons, or company licensed to manufacture, distribute, or redistribute devices.

II. Quality Assurance/Quality Control (QA/QC) Program

A QA/QC program consists of two parts. The first is the Quality Assurance (QA) program. This program is the planned and systematic actions necessary to provide confidence that a product will perform satisfactorily. The second part is the Quality Control (QC) program. A QC program provides a means to control and measure characteristics of an item, process or facility to the established requirements.

All vendors must implement and maintain a unique QA/QC program tailored to its needs. Any persons, materials, processes or services related to the manufacture, distribution or redistribution of any devices should adhere to the requirements of the QA/QC program.

The vendor must have a means of identifying the structure and components of the QA/QC program. These may be covered in the form of a manual that explains each component of the program and lists the procedures for implementing each component and the department responsible for implementing each component.

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This manual should be approved and signed by the head of each department involved. At a minimum, the QA/QC program should contain all the components that follow.

A. Organization.

Document the vendor's organizational structure starting with the Chief Executive Officer (CEO) down to the head of each department. Include all personnel in the QA/QC department along with their responsibilities. The organizational structure may be documented in the form of a flow chart with a brief explanation of each position and its responsibilities. The vendor's contact person, who is responsible for reporting defects or noncompliance to the agency, should also be noted in the organizational chart.

In the organization, the QA/QC director should report directly to someone in upper management who does not have direct responsibility for production. This person should have continued involvement in ensuring that the QA/QC department is running properly. The QA/QC director should have the authority to halt production at anytime to ensure that the device or production procedures conform to all regulations and specifications.

B. Personnel.

The vendor should have written procedures to ensure that each person has the appropriate qualifications and training for the job that they are performing. The vendor should keep records of each employee's qualifications, training (formal or informal), and a list of all persons qualified to perform special procedures or testing (e.g. welding, heat treating, weld inspections, etc.). The vendor should also keep necessary medical records (e.g. eye exams) that may affect the employee's performance because of the special procedures or testing.

C. Facility.

The physical layout of the facility should be mapped and posted. The map should indicate storage areas (devices, subassemblies and raw materials), production areas, inspection areas, and the shipping and receiving departments.

D. Equipment.

1. Use Log.

   The vendor should have a historical log of all the equipment that is either used in the production of the source, that enhances the quality of the source, or ensures that all rules are met. The log should include the following:

   a. manufacturer of the equipment;

   b. model and serial number; and

   c. instructions for use.

2. Maintenance Log.

   A maintenance log should be maintained and contain the following:

   a. records of all maintenance of all equipment;

   b. maintenance procedures;

   c. nature of the maintenance performed;

   d. date the equipment is due for maintenance;

   e. date the maintenance was performed; and

   f. frequency of routine maintenance.

3. Calibration log.

   The vendor must have a calibration log for all equipment used for measuring, testing, or inspecting The calibration log should include the following;

   a. manufacturer of the equipment;

   b. model and serial number of each piece of equipment;

   c. calibration procedures;

d. frequency of calibration;

e. name of each person qualified to calibrate the equipment;

f. date the equipment is calibrated; and

g. date of the next calibration.

All calibrations should be traceable to the National Institute of Standards and Technology (NIST).

The calibration frequency should be dependent upon the equipment's stability, purpose, and degree of usage. This frequency should also be left to the discretion of the QA/QC director. However, all new equipment or equipment that has undergone maintenance must be calibrated before use and no calibration interval should be greater than one calendar year.

Each piece of equipment must be traceable to its calibration record. Each piece of equipment should also be marked with its calibration date, next due date, and the name of the person who performed the calibration. If it is impractical for the equipment itself to carry such a label, its case should be labeled and the equipment made traceable to its case.

If calibration is performed by a subcontractor, a certificate from the subcontractor stating the date of calibration must be included in the calibration file. Subcontractors performing calibrations should demonstrate that all calibrations are traceable to NIST and should be subjected to periodic audits.

4. Special handling and storage.

If any equipment has special handling or storage procedures, the equipment or its case must be labeled with these procedures. If the procedure is too long to fit onto the equipment or its case, the procedure must be on file and a label specifying the location of the procedure must be attached to the equipment or its case.

E. Design and document control.

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The vendor must have written procedures to ensure that all documents (drawings, procedures, etc.) used in the manufacturing process conform to the rules and pertinent conditions of the license. The procedures should include special instructions for labeling, cleaning, handling, equipment settings, shipping, packaging, and storage. They should also contain special procedures with lists of materials, dimensions with tolerances, and special finishes that need to be applied. These procedures should also require that drawings show changes and revision levels.

The procedures should ensure that each document is released only after it has been reviewed and approved by someone other than the person who prepared that document.

Records of all appropriate documents must be kept. The records must include design and documentation changes, dates of changes and the reasons for the changes.

F. Material/service procurement.

All materials and procedures used to produce a device must meet pertinent rules and specifications. In all cases, the applicant should have written procedures for ordering materials or services, receipt inspection, and auditing of subcontractors. Suppliers should demonstrate that they are capable of suppling materials or services in accordance with the rules and specifications. This may be accomplished in one of the following ways:

1. All subcontractors should perform periodic audits of their QA/QC procedures at intervals of three years or less. The subcontractor's QA/QC program may meet the same requirements as the vendor's program. If the subcontractor's program meets the minimum requirements established by the vendor, then the receipt inspection of the subcontractor's products need only be a visual inspection (correct paperwork, dimensions, damage, etc.). A receipt inspection procedure should include provisions for nonconforming materials. Records should be maintained of all orders, inspections, and audits.

2. Perform a complete inspection of a sample of each lot received from the subcontractor to confirm that each item in the lot conforms to all specifications and requirements. Remember that sample sizes should conform to Military Standard 105 (MIL-STD-105).

In addition, the vendor should have a list of approved subcontractors from which each item or service may be procured.

Upon issuance of an order for materials or services, the purchase order should contain the following.

- scope of the work
- technical requirements
- identification of the documents to accompany the order
- identification of records kept on file by the vendor
- requirements reporting/approving nonconforming product
- dates ordered and due
- authorized purchasing agent's signature

A written contract with the subcontractor may contain some of the information above and not have to be included in the purchase order.

G. Inventory.

Written inventory procedures should include instruction for special handling, marking, tagging, labeling, segregating, paperwork manipulation, and handling of nonconforming materials.

The inventory system should account for material having a shelf-life. It should also account for all subassemblies, as well as the finished product. The inventory system should also document that finished products have completed final inspection and testing and when this was accomplished.

H. Assembly procedures.

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Procedures for the assembly process should include step-by-step instructions to accomplish each task, including identification of any machinery or other equipment needed for the task, the qualifications of the worker performing the task, and any precautions or special notices. These procedures should also describe the inspections and testing that should be performed and when each inspection and/or test is to be performed. Mundane tasks need not be explained in detail since all procedures should be performed by qualified personnel (e.g. procedures on how to mill a part to size need not be explained in full since a qualified machinist will be performing the task).

I. Inspection/testing.

The vendor must make certain that all subassemblies, assemblies, devices and production procedures conform to the appropriate engineering drawings, specifications, and rules. This is done by following written procedures for in-process and final inspection and testing of the device and for inspection of production processes. Acceptance criteria, receipt inspection, inspection of production procedures, a schedule of the points in the production process where testing or inspection is performed, procedures for generating sample sizes, final inspection and testing, packaging and transportation inspections, provisions for bypassing tests or inspections and provision for what to do with nonconforming materials should be included in the inspection and testing procedures.

Documentation of inspection and test results should be maintained for inspection by the agency. Aside from the actual results of the inspection or test, this documentation should also include the date and identification of the person performing the inspection or test.

The agency will verify that the vendor have a means of separating a product that has been inspected/tested from a product that has not. The agency will also verify that the final product undergoes 100 percent operational testing and the removal of 100 percent of all removable contamination before release from the manufacturing facility.

J. Nonconforming materials.

Nonconforming materials may be discovered at any time during the receipt

inspection, the manufacturing process, or the final inspection or testing of the device. These materials may also be discovered by the customer.

The vendor should have procedures describing how to handle these materials. Some of the items discussed should include how to separate nonconforming materials from production and/or tagging them for ease of identification. There should also be provisions for reintroducing nonconforming materials back into production after the nonconformance has been corrected, such as reinspection and/or testing. A record should be maintained documenting the nonconforming materials and their fate (reintroduction into the manufacturing process or disposal).

K. Packaging and transportation.

Procedures for packaging and transporting any item, sub-assembly, or device should be written to ensure that any rule or specification governing those materials will be met. These procedures should also include a discussion of inspections and the appropriate records documenting this activity.

The procedures for packaging completed devices should ensure that all paperwork and manuals (instructions, maintenance procedures, packing lists, etc.) are included with the device.

L. Defects and customer complaints.

Specific procedures for evaluating and recording defects and customer complaints should be provided. Each defect or customer complaint received by the vendor should be recorded and investigated. The record for the defect should contain the following information:

- device type and model number
- serial number
- cause of failure
- analysis of failure
- corrective action taken

If a customer complaint is received, the record should contain the following additional information.

- $ name of the complainant
- $ nature and date of complaint
- $ reply to complaint

After the investigation is completed, the procedures should require that the QA/QC department, the department responsible for the failure/complaint, and any licensees who may be affected are notified of the defect/complaint and the corrective action.

Also, procedures requiring a trend analysis on all defects/complaints should be included in this section. This analysis should be performed at intervals no greater than one year.

M. Audits of QA/QC programs.

Procedures for auditing the vendor's QA/QC program and each subcontractor's QA/QC program should describe acceptance criteria for each step in the manufacturing process and a review of all procedures to insure all procedures are current.

The personnel performing the audits should be properly trained and qualified. Audits should be conducted by individuals not involved in the area(s) covered by the audit. However, this may be waived if the integrity of the QA/QC program is not compromised. If a waiver is sought, a justification for the waiver and evidence that the QA/QC program will not be compromised should be submitted to the agency for approval.

Records of audits should be retained for inspection by the agency and all personnel responsible for the matters being audited. These records should include items checked during the audit, deficient areas and should be signed and dated by the appropriate company officer. If the audit is concerned with quality, it should be performed at intervals of no less than one year.

N. Records and documentation.

The QA/QC department must maintain current copies of the QA/QC procedures manual and all records associated with the QA/QC program. The records must be maintained for inspection by the agency and must be retained for at least three years.